

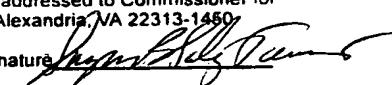


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No: 10/540,296  
 Applicant(s): Miragaya, et al.  
 Filed: June 21, 2005  
 Title: Formulations for the Rectal Administration of Thrombolytically-Active agents  
 TC/A.U.: Unassigned  
 Examiner: Unassigned  
 Docket: 976-28 PCT/US

Mail Stop Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450

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on 9/9/05 Signature 

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In order to fulfill the requirements of candor and good faith set forth in the 37 C.F.R. §1.56, Applicant submits herewith the following Information Disclosure Statement in accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

**UNITED STATES PATENTS**

<u>PATENTEE</u>	<u>PATENT NO.</u>	<u>ISSUE DATE</u>
Barron, et al.	6,440,947 B1	August 27, 2002

**FOREIGN PATENT DOCUMENTS**

<u>COUNTRY</u>	<u>PUBLICATION NO.</u>	<u>PUBLICATION DATE</u>
EPO	EP 0 340 933 A	November 8, 1989
EPO	EP 0 672 659 A	September 20, 1995

**NON-PATENT PUBLICATIONS**

1. Sumi, et al., "Activation of plasma fibrinolysis after intrarectal administration of high molecular urokinase and its derivative," *Acta Haemat.* 1983, Vol. 70, 289-295.
  
2. MacKay, et al., "Peptide drug delivery; Colonic and rectal absorption," *Advanced Drug Delivery Reviews*, 1997, Vol. 28, 253-273.

Each of the above references were listed in the International Search Report issued in the corresponding International Application. A copy of the International Search Report accompanies this IDS.

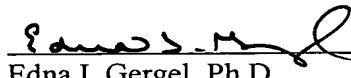
Copies of the cited references should have been provided by the International Searching Authority. Upon receipt of a Notification of Acceptance of Application indicating what items have been received by the Patent and Trademark Office, Applicant will review the same to ensure that the references were provided.

A separate listing of all the references has been set forth on the enclosed form PTO-1449. The Examiner is respectfully requested to consider these references in their entirety, and to indicate that he or she has done so by initialing the enclosed Patent and Trademark Office Form 1449.

If the Examiner has any questions relating to the present communication he or she is invited to contact Applicant's agent at the telephone number set forth below.

Applicant does not believe that any fees are due. However, if any [redacted] are due, please charge Deposit Account No. 08-2461.

Respectfully submitted,

  
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Edna I. Gergel, Ph.D.  
Registration No.: 50,819  
Agent for Applicant(s)

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(516) 822-3550  
EIG:sbs

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 976-28 PCT/US	SERIAL NO. 10/540,296
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Miragaya, et al.	CONFIRMATION NO. Unassigned
(Use several sheets if necessary)		FILING DATE June 21, 2005	GROUP Unassigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	6,440,947 B1	Aug. 27, 2002	Barron, et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION
						YES NO
	EP 0 340 933 A	Nov. 8, 1989	EPO			
	EP 0 672 659 A	Sept. 20, 1995	EPO			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Sumi, et al., "Activation of plasma fibrinolysis after intrarectal administration of high molecular urokinase and its derivative," <i>Acta Haemat</i> , 1983, Vol. 70, 289-295.
		MacKay, et al., "Peptide drug delivery; Colonic and rectal absorption," <i>Advanced Drug Delivery Reviews</i> , 1997, Vol. 28, 253-273.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.